

REMARKS:

In response to the Office Action mailed October 18, 2007, claims 1, 3, 23, 26, 29, and 31 have been amended. The amendments are supported throughout the specification, e.g., in paragraphs [0018], [0033], [0035], [0043], and [0044], and in the drawings, e.g., in FIGS. 6B and 6C. No new matter has been introduced.

In the Office Action, claims 1, 7, 9-11, 13, 15, 23-31, and 33-34 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 7,169,172 (“the Levine et al. reference”), and claim 1 was rejected under 35 U.S.C. § 102(a) as anticipated by U.S. Publication No. 2003/0050684 (“the Abrams et al. reference”). Finally, claims 2-6, 8, 12, and 14 were rejected under 35 U.S.C. § 103(a) as unpatentable over the Abrams et al. reference. Because neither of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, the rejections should be withdrawn.

Turning first to the Levine et al. reference, a device 100 is disclosed for caged delivery of a stent or graft within a body lumen that includes a plurality of arms 104 attached to a distal end of a tubular portion 102 and a mechanism to open the arms. Col. 4, lines 22-28. Initially, the arms 104 define a cage 106 for containing a stent 108 in a constricted form. Col. 4, lines 28-30. In operation, the cage 106 carries the stent 108 to a treatment site, whereupon the arms 104 are opened, allowing the stent to be released from the cage. Col. 4, lines 32-35. In one embodiment, a pullwire 414 is attached the arms 104 that may be pulled to retract the arms 104 proximally within a catheter 118. Col. 6, lines 44-47. Thus, the Levine et al. reference does not disclose,

teach, or suggest a locator that is initially retracted within a sheath and that assumes an expanded configuration when extended from the sheath.

Turning to the present claims, claim 1 recites an apparatus for locating an interventional device relative to the ostium of a branch vessel that includes a sheath having proximal and distal ends, and a lumen extending therebetween, the sheath adapted to be affixed to an interventional device; and an ostial locator wire slidably disposed within the sheath, the ostial locator wire having a distal region initially provided in a retracted configuration within the sheath that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially encircles and is spaced apart from an interventional device when the sheath is affixed thereto and that assumes the retracted configuration when retracted back into the lumen, the sheath being advanceable with the distal region in the expanded configuration to position the interventional device relative to the ostium, the ostial locator wire and sheath being removable after positioning the interventional device.

First, as explained above, the Levine et al. reference fails to disclose, teach, or suggest an ostial locator wire that is *initially provided in a retracted configuration* within a sheath lumen and that assumes an expanded configuration when extended from the sheath, as claimed. In direct contrast, the Levine et al. arms 104 are initially provided in an expanded configuration and, in one embodiment, *thereafter* may be retracted into a catheter 118. The expanded configuration of the arms 104 is necessary to contain the stent 108 in a constricted form, and therefore it would not be possible to provide the arms 104 initially within the catheter 118 without releasing the

stent 108, which would allow the stent 108 to expand and preclude delivery of the stent 108 into a patient's body.

Second, the Levine et al. reference does not teach or suggest an ostial locator wire that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially *encircles and is spaced apart* from an interventional device when the sheath is affixed thereto. Instead, the Levine et al. arms 104 are not spaced apart from an interventional device, but are necessarily in contact with the stent 108 to contain the stent 108 in its constricted form during delivery. For these reasons, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Levine et al. reference.

For similar reasons, independent claims 23 and 29, and their dependent claims, are neither anticipated by nor otherwise obvious over the Levine et al. reference. In addition, claim 29 recites that the distal region assumes a shape in the expanded configuration that is flattened out axially when the sheath is advanced into an ostium, thereby providing tactile feedback regarding the position of the distal region. The Levine et al. reference fails to disclose, teach, or suggest a distal region that can be flattened out *axially* when advanced into an ostium. In one embodiment, shown in FIGS. 3A and 3B, the Levine et al. arms 104 may be expandable and collapsible *radially*, but not axially. As explained in the Levine et al. reference, collapsing the arms radially inwardly may further restrain the stent therein. Col. 5, lines 27-29.

Unlike radially collapsible arms, the claimed locator wire can be flattened out axially after being expanded, which may provide the user “with tactile and visual feedback regarding the position of the distal region of the locator wire and attached interventional device,” as explained

in paragraph [0035] of the present application. See also paragraphs [0012], [0016], [0019]. For example, as explained in paragraph [0043] of the present application, as the locator wire is flattened axially, “the clinician will sense the increased resistance to advancement of catheter 30 and ostial locator device 10, and informing the clinician that the stent is properly positioned.” The Levine et al. reference fails to disclose, teach, or suggest such a tactile feedback to facilitate positioning a stent within a patient’s body.

Further, if the Levine et al. arms were collapsible axially, they would risk crushing the stent between the ends of the arms, e.g., when the device was advanced into a bend or other location that created axial resistance to advancement of the device. Accordingly, for this additional reason, claim 29 (and similarly claims 13 and 26) would not be anticipated by or otherwise obvious over the Levine et al. reference.

Turning to the Abrams et al. reference, a restraint is disclosed for delivering a self-expanding stent. As shown in FIG. 1, a delivery system 10 includes a catheter 12 including a retaining wire 24 that is coiled about a stent 34 to retain the stent 34 in a reduced profile configuration. Paragraphs [0040]-[0043]. When a pull back wire 16 is drawn proximally, the retaining wire 24 is retracted from about the stent 34 and into a lumen 14 of the catheter 12. Paragraph [0044]. Once the wire 24 is withdrawn from around the stent 34, the stent 34 is allowed to fully expand, i.e., because the stent 34 is self-expanding. Paragraph [0044].

Thus, the Abrams et al. reference also fails to disclose, teach, or suggest an ostial locator wire that is *initially provided in a retracted configuration* within a sheath lumen and that assumes an expanded configuration when extended from the sheath, as recited in claim 1.

Instead, even if the coiled configuration of the Abrams et al. retaining wire could constitute an expanded configuration, as claimed (which Applicant does not concede), the retaining wire is necessarily initially provided in this “expanded configuration.” Otherwise, similar to the Levine et al. cage, the stent would be released and free to fully expand, which would preclude delivery into a patient’s body.

Further, as explained in Applicant’s previous response, the Abrams et al. reference fails to disclose, teach, or suggest an ostial locator wire that assumes an expanded configuration when extended from the distal end of the sheath such that the distal region partially encircles and *is spaced apart from an interventional device* when the sheath is affixed thereto. In contrast, the Abrams et al. retaining wire must be disposed around and in contact with the stent to prevent the stent from expanding until the wire is retracted. Thus, the Abrams et al. retaining wire cannot be spaced apart from the stent without deploying the stent. Accordingly, for these reasons, claim 1 and its dependent claims are neither anticipated by nor otherwise obvious over the Abrams et al. reference.

For similar reasons, claims 23 and 29 and their dependent claims are also neither anticipated by nor otherwise obvious over the Abrams et al. reference. Further, with respect to claim 29, the Abrams et al. reference does not teach or suggest a locator wire including a distal region that assumes a shape in the expanded configuration that is *flattened out axially* when the sheath is advanced into an ostium. Instead, the Abrams et al. reference merely discloses a retaining wire that must remain around a self-expanding stent to prevent premature deployment of the stent. If the Abrams et al. retaining wire were somehow flattened axially while disposed

around a stent, it would no longer prevent expansion of the stent, which would risk premature deployment of the stent. Accordingly, for this additional reason, claim 29 and its dependent claims are neither anticipated by nor otherwise obvious over the Abrams et al. reference.

In view of the foregoing, it is submitted that the claims now presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

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